Attachment 2

Title 8, Chapter 63 — Chapter Notes

CHAPTER AUTHORITY: N.J.S.A. 26:5C-25 et seq., particularly 27, 28, and 31.

CHAPTER SOURCE AND EFFECTIVE DATE:

R.2007 d.142, effective April 9, 2007.
See: 39 N.J.R. 1805(a).

CHAPTER EXPIRATION DATE:

Pursuant to N.J.S.A. 26:5C-31b, these rules shall not expire until rules are adopted pursuant to N.J.S.A. 26:5C-31a.

CHAPTER HISTORICAL NOTE:

Chapter 63, Certification as a Narcotic and Drug Abuse Treatment Center, was adopted as R.1971 d.205, effective November 15, 1971. See: 3 N.J.R. 202(a), 3 N.J.R. 256(c).

Chapter 63, Certification as a Narcotic and Drug Abuse Treatment Center, expired on July 7, 2002.

Chapter 63, Sterile Syringe Access Program Demonstration Project Rules, was adopted as special new rules by R.2007 d.142, effective April 9, 2007. See: Source and Effective Date.

Chapter Notes

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§ 8:63-1.1 Purpose; scope

(a) The purpose of this chapter is to implement P.L. 2006, c. 99, §§ 3, 4, and 7 (approved December 19, 2006).

(b) This chapter applies to:

1. Municipalities that seek to establish or authorize the establishment of a sterile syringe access program to provide for the exchange of hypodermic syringes and needles;

2. Operators and employees of entities that seek to apply to operate sterile syringe access programs; and

3. Consumers of the products and services of sterile syringe access programs

§ 8:63-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Act" means the Bloodborne Disease Harm Reduction Act, P.L. 2006, c. 99.

"AIDS" means Acquired Immunodeficiency Syndrome.

"Commissioner" means the Commissioner of the Department of Health and Senior Services.

"Federally-qualified health center" means an entity approved as a Federally-qualified health center by the Centers for Medicare and Medicaid Services pursuant to Section 1905(l) of the Social Security Act, 42 U.S.C. §1396d(l), and licensed as an ambulatory care facility pursuant to N.J.S.A. 26:2H-1 et seq. and N.J.A.C. 8:43A.

"HIV" means Human Immunodeficiency Virus.

"IDU" means injection drug use.

"Operational guidelines" means the Operational Guidelines for a Demonstration SSAP, provided at the chapter Appendix, incorporated herein by reference.

"Operator" means one or more of the following entities:

1. A hospital or other health care facility licensed pursuant to P.L. 1971, c. 136 (N.J.S.A. 26:2H-1 et seq.);

2. A Federally-qualified health center;

3. A public health agency;

4. A substance abuse treatment program;

5. An AIDS service organization; or

§ 8:63-2.1 Prerequisites applicable to municipalities with respect to Department consideration of SSAP application

(a) The following are eligibility prerequisites to the Department's consideration of an application for approval of a sterile syringe access program by or on behalf of a municipality (hereinafter referred to as "eligibility prerequisites"):

1. The establishment of an ordinance authorizing the operation of an SSAP that satisfies the requirements of the Act, particularly N.J.S.A. 26:5C-27 and 28, by the governing body of the municipality on behalf of which an applicant seeks to establish an SSAP;

2. The residence of at least 350 people living with HIV or HIV/AIDS in the municipality on behalf of which an applicant seeks to establish an SSAP; and

3. A prevalence rate of HIV attributable to IDU of at least 300 persons per 100,000 population in the municipality on behalf of which an applicant seeks to establish an SSAP.

i. "Attributable to IDU" includes: injection drug user, men who have sex with men and inject drugs, or sex with an injection drug user.

(b) In addition to (a) above, municipalities shall meet applicable requirements in the Operational Guidelines, and applicable conditions contained in the notice of request for applications described in N.J.A.C. 8:63-2.4 below.

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§ 8:63-2.2 SSAP applicant eligibility criteria

(a) An applicant for Commissioner-approval of an SSAP shall be either:

1. A municipality that meets the eligibility prerequisites at N.J.A.C. 8:63-2.1; or

2. An operator acting with respect to a municipality that meets the eligibility prerequisites at N.J.A.C. 8:63-2.1, either pursuant to a contract with the municipality or independently.

(b) In addition to (a) above, applicants for Commissioner approval of an SSAP shall meet applicable requirements in the Operational Guidelines.

§ 8:63-2.3 Authorized number of SSAPs in demonstration project

The Department shall authorize the establishment of up to six SSAPs for the purpose of the demonstration project established pursuant to the Act.

§ 8:63-2.4 Publication of notice of request for applications

The Department shall announce a request for applications to participate in the demonstration project through the establishment of an SSAP in a notice of request for applications published in the New Jersey Register.

§ 8:63-3.1 Form of uniform identification card

(a) Pursuant to N.J.S.A. 26:5C-28b(8), the Commissioner has approved a form of uniform identification card for consumers, staff, and volunteers of SSAPs.

(b) The identification card contains the following statement:

"The holder of this card is a participant of the [name of SEP] Syringe Exchange Program (SEP). The SEP is a public health program established by the [sponsoring municipality or sponsoring agency]. The holder of this card has been instructed and has indicated a viable understanding that the privilege of possessing a syringe(s) while enrolled as a participant in the SEP is deemed to constitute a privilege to be exercised within the boundaries of the municipality issuing the syringes by the SEP.

For more information please contact: [name, address, and telephone number of sponsoring municipality or sponsoring agency]."

(c) Each identification card shall contain a registration number, which shall be linked to an unique identifying number based on a confidential formula and maintained by the SEP.

APPENDIX

DEMONSTRATION SYRINGE EXCHANGE PROGRAM

OPERATIONAL GUIDELINES

New Jersey Department of Health and Senior Services

Public Health Services Branch

Division of HIV/AIDS Services

Operational Guidelines for a Syringe Exchange Program

[] Municipal Requirements

[] SEP Site Location

[] New Sites and Expanding/Changing Site Location

[] Access and Outreach

[] Disease Prevention Information

[] Communication with the Community

[] Determining Participant Eligibility

[] Obtaining and Recording Participant Information

[] Participant Registration Identification Cards

[] Face to Face Intervention

[] Syringe Exchange Protocol

[] Termination of Program Participants

[] Syringes and Other Supplies

[] Collection and Storage of Used Syringes and RMW

[] Transport and Disposal of RMW

[] Prevention of Needlestick Injuries

[] Developing Referral Linkages

[] Required Training

[] Reporting Community and Law Enforcement Concerns

[] Evaluation

Operational Guidelines for a Demonstration Syringe Exchange Program

in New Jersey

The Division of HIV/AIDS Services, Public Health Services Branch, within the Department of Health and Senior Services prepared the Syringe Exchange Program (SEP) Guidelines in accordance with the provisions of the Bloodborne Disease Harm Reduction Act, P.L. 2006, c. 99 (the "Act"). The SEP Guidelines apply to all municipalities applying for and participating in a syringe exchange program. The SEP Guidelines shall be used by approved municipalities to ensure that New Jersey SEPs comply with standards and procedures that maximize the safety of participants, health care workers, and the public; and assures the qualitative implementation of this initiative. The Commissioner of Health and Senior Services may select up to six municipalities to implement a demonstration SEP.

Municipalities shall be selected through a Request for Application (RFA) process restricted to those municipalities that first, have enacted an ordinance which authorizes the establishment of an SEP; second, have a minimum of 350 cases of individuals living with HIV/AIDS; and third, have a prevalence rate attributable to injection drug use of at least 300 per 100,000 population. The designation of a municipality as a participating SEP will be based upon the comprehensiveness of the applicant's submitted plan that addresses each of the organizational guidelines below, the required components of the application, and the data collection requirements.

Organizational Guidelines

1. Municipal Requirements.

Municipalities shall:

a) Adopt an ordinance that authorizes the establishment of an SEP (Two or more municipalities may jointly establish or authorize establishment of an SEP, provided each municipality meets all requirements as described in this section.);

b) Have a minimum of 350 cases of individuals living with HIV/AIDS as of December 31, 2006;

c) Have a prevalence rate attributable to injection use of at least 300 per 100,000 population;

d) Have evidence of local drug treatment capacity to provide referral or treatment in a variety of care modalities;

e) Have the experience and capacity to provide HIV services, and to coordinate the delivery of services for other blood-borne pathogens; and

f) Authorize an agency or program (the Program) to run the SEP. The authorized Program must be a:

i) A non-profit corporation, such as an HIV/AIDS service organization, drug abuse treatment program, acute care hospital, other healthcare facility, Federally-qualified health center; and/or

ii) A unit of a local or municipal government agency, such as a local health department or other public health agency.

2. SEP Site Location. Each applicant must designate a stationary or mobile site (site) location for the SEP. Sites should be easily accessible to potential participants, but must not be located near a school zone, playground, or other setting not appropriate to conduct such a Program. Representatives of the SEP are encouraged to meet with community residents, community business owners, community-based organizations, health care, drug treatment and social service providers, law enforcement officials and potential SEP participants to determine support for program services. The applicant shall document the following:

a) The proposed site location and total hours of operation, which may be intermittent or consecutive hours, but shall be no less than five hours per week;

b) A description of the Program's previous and planned activities to interact with a community where the SEP site is planned;

c) Any issues regarding community concerns including plans regarding clean-up and maintenance of the SEP site; and

d) A description of coordination of services provided at the site with other linkage services in the community.

3. New Sites and Expanding or Changing Existing Site Locations. SEPs, which plan to open a new site(s) or expand or change an existing site location, should submit a formal written request to the governing municipality, prior to the proposed opening of the site, specifying the proposed sites and hours of operation. The request to establish a new site or to change an existing site shall address all of the requirements of Paragraph 2 above, as appropriate.

All new sites must be operated consistently: at least once a week, at the same time each week, which may be intermittent or consecutive hours, but shall be no less than five hours per week.

4. Access and Outreach. SEPs may use a broad range of points of access in order to reach and provide services to as diverse a group of people as possible. SEP participants shall be treated in a manner that promotes enrollment, participation and retention.

5. Disease Prevention Information. Syringes, disease prevention materials, harm reduction, and risk reduction information shall be provided through the Program at no cost to participants. Confidentiality of participants will be maintained at all times. The Program shall have policies in place to protect medical information consistent with State and Federal law, including the Health Insurance Portability and Accountability Act (HIPAA). Services will be provided in a manner that is culturally and linguistically appropriate.

6. Communication with the Community. The SEP shall demonstrate good faith efforts to provide information regarding the scope of services provided by the Program and shall maintain open communication with the community at large, including local government, health care providers, law enforcement and others.

7. Determining Participant Eligibility. On the participant's first visit to the SEP, appropriate Program staff or volunteers will determine eligibility. Individuals wishing to participate in the Program must be an active IDU, who is 18 years of age or older.

8. Obtaining and Recording Participant Information. On the participant's first visit to the SEP, the Program staff or trained volunteers will determine and record the age, race, ethnicity, gender and home zip code of the participant. SEP agrees to obtain and record participant information, such as history of injection drug use, drug of choice, drug treatment status, drug and sexual risk behaviors and involvement in other public health and social services, as required by evaluation project protocol.

9. Issuing Participant Registration Identification Cards. All SEP participants must be provided with identification cards and assigned an I.D. code. Identification cards will be issued by the Program and all cards will contain uniform information. Cards will be coded by Program staff or volunteers with an anonymous registration number for each participant, which the Program must record during subsequent exchange transactions to collect program utilization information. All SEP participants will be instructed to carry the participant registration identification cards with them.

Each SEP participant's registration number will be linked to a unique identifier (I.D. code) maintained by the SEP. Although the formula or algorithm for constructing the unique identifier may vary from program to program, it should consist of a combination of letters and numbers usually representing the participant's or his or her parent's initials, year of birth, zip code, etc., and be approved by the DHSS-DHAS.

This identification card must state that "The holder of this card is a participant of the [name of SEP] Syringe Exchange Program. The SEP is a public health program established by the [sponsoring municipality or sponsoring agency]. The holder of this card has been instructed and has indicated a viable understanding that the privilege of possessing a syringe(s) while enrolled as a participant in the SEP is deemed to constitute a privilege to be exercised within the boundaries of the municipality issuing the syringes by the SEP. For more information please contact: [name, address, and telephone number of sponsoring municipality or sponsoring agency]."

The privilege referenced in the above paragraph refers to the governing municipality's statutory authority to approve the creation and operation of the SEP.

10. Face-to-Face Intervention. Syringe exchange will only take place in a face-to-face interaction between the SEP participant and appropriate Program staff and/or volunteers. Syringes shall not be exchanged via mail.

11. Syringe Exchange Protocol. SEPs should strive for one-for-one syringe exchanges. The exchange protocol for each Program may vary slightly from the model outlined below in terms of the number of syringes dispensed to the participant on the initial visit, and the maximum number of syringes distributed per exchange transaction based upon each Program's number of exchange sites and the days and hours of operation.

a) Initial Encounter. At the initial encounter, an assessment of need will be made to determine the number of syringes that will be provided. The staff person and the participant will discuss how many times a day/week the participant injects, and how often they will be able to come to an exchange site. Based on this information, a determination will be made on how many syringes are needed to insure that the participant will have sufficient syringes for a single injection per syringe.

b) Subsequent Encounters. At subsequent encounters, the normal exchange strives for one-for-one syringe exchange. Program staff and/or volunteers work with the participant to determine the maximum number of syringes needed based on each participant's individual drug use (type of drug(s) used, frequency of injection, frequency of visits to the exchange program, etc.). Participants are instructed to return all used syringes upon returning to the SEP. The Program will strive to dispense one syringe per each syringe returned, but may dispense up to 10 more based on the Program's written exchange procedures.

c) Contingencies. If a participant does not return all dispensed syringes, Program staff will determine the appropriate number of syringes to dispense on a case-by-case basis, depending on the participant's need and circumstances, overall program participation and the previous syringe return rate. Examples of contingencies or emergencies may be theft or loss of syringes.

12. Termination of Program Participants. A participant who commits any of the following acts will be subject to termination from the Program at the discretion of the Program director:

a) Violent behavior against Program staff, volunteers, or other Program participants;

b) Selling or purchasing syringes; and/or

c) Selling or purchasing illicit drugs on site.

Participants who are terminated from an SEP will be provided with the reasons for such termination. Participants terminated from an SEP shall return the participant registration identification card to the SEP.

13. Syringes and Other Supplies. Each Program shall establish policies and procedures for identification and authorization for ordering, receiving, storing, dispensing, and disposing of syringes and other supplies. These procedures include appropriate security precautions and methods for maintaining up-to-date inventory records. In order to prevent possible theft or loss of Program supplies, the following operational procedures should be observed:

a) Storage of New Syringes. New syringes must be stored in a locked, secured space at the program site and only authorized individuals should have access to locked storage facilities.

b) Ordering and Reporting on Access to Syringes and Other Supplies. Only those Programs authorized by the governing municipality are permitted to obtain and store syringes for the SEP. Each Program shall establish a policy documenting authority of individuals permitted to order and access syringes. SEPs should designate one primary person and may identify an alternate to be responsible for ordering and reporting on utilization of supplies. Only those persons will be authorized to sign supply order forms and have access to locked storage facilities.

c) Handling Supplies. Supplies must be kept within sight of Program staff and volunteers at all times during SEP operations. All Program staff and volunteers are responsible for observing proper security precautions. However, one properly trained individual should be designated as having primary responsibility for security of supplies during SEP operations at each site.

d) Storage and Disposal of Used Syringes. Each Program must adhere to Federal and State law and regulations regarding the timely disposal of all used injection equipment and other medical infectious waste. Medical waste becomes regulated at the point of generation and is subject to the procedures for storage and disposal in accordance with Occupational Safety and Health Administration (OSHA) OSH Act of 1970 (29 U.S.C. § 651) and Public Employees' Occupational Safety and Health (PEOSH) (N.J.S.A. 34:6A-25) rules and guidelines. Each Program is required to establish and follow these policies and procedures for the collection, generation, storage, transportation and disposal of Regulated Medical Waste (RMW) governed by N.J.A.C. 7:26-3A.

e) Theft of Supplies. Upon the discovery of a theft of supplies, a report must be filed with the police and the governing municipality no later than 24 hours after discovery. The governing municipality may require more restrictive notice requirements.

f) Return of Keys. Written record of the names, addresses, and telephone numbers of the people who possess keys to the storage area must be maintained by each Program. Keys to storage facilities must be returned to the Program immediately upon termination of an individual's employment or volunteer status or when authorization for possession of keys is withdrawn.

14. Collection and Storage of Used Syringes and Regulated Medical Waste. Used syringes should be separated from other regulated medical waste. The following operational procedures should be observed:

a) Federal and State law and regulations: Consistent with all Federal and State law and regulations, all used syringes must be placed in approved leak proof, rigid, puncture-resistant containers that are conspicuously labeled "Infectious Medical Waste" and all other regulated medical waste must be placed in red, disposal moisture proof, rip-resistant bags.

b) RMW storage: RMW may be stored at the point of generation until it can be transported to the proper facility for disposal. If waste is stored before transporting, the used syringes must be kept in a locked, secured area of the Program site,

and only authorized individuals may have access to locked storage facilities. Used injection equipment must be stored in appropriate hazardous waste containers at all times.

15. Transport and Disposal of RMW. At each SEP site, an individual(s) will be authorized to transport RMW. The governing municipality will assure that the individual(s) receive training on Federal and State law and regulations regarding regulated medical waste, and the individual(s) will be listed on all relevant RMW transport documentation as being responsible for transporting for that SEP site.

16. Prevention/Treatment of Needlestick Injuries and Bloodborne Pathogens Exposures. Each employer (public and private) of Syringe Exchange Program staff (employees and volunteers) must demonstrate compliance with the Bloodborne Pathogens Standard (29 CFR 1910.1030). As required by the standard, each employer must have a written Exposure Control Plan in place that addresses the unique exposure risks associated with SEP tasks and settings. Some provisions of the standard include: determinations of which staff/volunteers are at risk of exposure, provision of hepatitis B vaccine, methods of preventing needlestick and other bloodborne pathogens exposures (including engineering controls, good work practices, personal protective equipment, housekeeping, and contaminated sharps discarding and containment), procedures for immediate post-exposure treatment and follow-up if SEP staff experience a needlestick or exposure, initial and annual training that covers the content required by the standard. Each employer is required to establish and maintain the records required by the standard. All SEP program staff and volunteers are responsible for observing proper safety and security precautions during SEP operations.

17. Developing Referral Linkages. All SEPs should identify referral relationships with other services, including, but not limited to: HIV antibody testing services; HIV and primary health care services; family planning, prenatal and obstetrical care; immunizations; substance abuse treatment; tuberculosis screening and treatment; screening and treatment for sexually transmitted diseases; screening and treatment for hepatitis B and C; case management and support services for HIV-infected people, mental health and other social services.

a) Recording Referrals. Referrals made on behalf of SEP participants must be recorded by the Program, including the date of the referral, the date by which the referral was completed, if known, and the type of service to which the referral is made. Quarterly summaries of all referrals must be reported to the governing municipality, or to the health authority designated by the governing municipality.

b) Tracking Referrals. Programs will track referrals by encouraging participants to self-report the outcome of the referral and follow-up directly with the agency to which the participant has been referred. When a Program has a referral specialist on staff, the Program should follow-up with the referred agency on as many referrals as possible and should document outcomes.

18. Training of SEP Staff and Volunteers. All SEP staff and volunteers, who collect syringes, or who distribute syringes, condoms, bleach kits or other prevention materials, or who make referrals to other services for participants of the SEP, must complete a proper course of training, and be regularly supervised. The Program shall identify appropriate levels of staff expertise in working with IDUs and provide adequate staff training. Training may be provided by a) approved SEPs; b) the New Jersey Department of Health and Senior Services (NJDHSS); and c) other sources. Staff of the DHAS/DHSS will assist Programs in developing curricula, arranging and facilitating training provided by the NJDHSS and identifying and coordinating training provided by other sources. It is recommended that resources be identified among individuals and agencies that have experience and a record of accomplishment in the operation of SEPs. All SEPs are required to provide training on topics including, but not limited to, those provided below:

a) Procedures for handling potentially infectious injection equipment, disposal of hazardous waste, universal precautions, the prevention and handling of needlestick injuries and control of exposure to blood-borne pathogens, including HIV and hepatitis B and C, tuberculosis, and injury reporting procedures. Training is required for all SEP staff and volunteers;

b) Procedures to ensure that syringes are properly secured and that their handling and disposal is safeguarded and in accordance with State and Federal law and regulations;

c) Harm reduction and the hierarchy of risks associated with sexual and drug-using behaviors and risk reduction practices for those behaviors;

d) Methods of outreach to engage target populations in Program activities;

e) Procedures for making referrals to other services, including primary care, drug treatment, HIV counseling and testing, prenatal care, screening and treatment of sexually transmitted diseases, and other HIV support and social services;

f) Cultural diversity of the participant populations, including sensitivity to the needs of injecting drug users, people of color, women, gay men and lesbians, sex workers, and transgendered populations;

g) Overview of diseases prevalent in substance using populations, including sexually transmitted diseases, hepatitis A, B and C, pneumonia, and skin abscesses; including infection control precautions for SEP staff and volunteers and the names of providers where these services can be obtained;

h) Basic overview of HIV disease, including modes of transmission, prevention, spectrum of illness, opportunistic infections and approaches to treatment; and

i) Basic overview of addictions and drug treatment.

19. Reporting Community and Law Enforcement Concerns. Incidents involving the SEP, including community objections or concerns about SEPs, law enforcement episodes, violence at SEP sites, needlestick injuries, theft of supplies and potential legal action against the Program, must be documented and reported to the appropriate municipal authority. Incident reports must be forwarded to the governing municipality, as required by the governing municipality but, no later than within 24 hours of occurrence. The purpose of these reports is to ensure that documentation of incidents exists in order to identify and address potential problems that may have an adverse impact on the provision of services.

20. Evaluation. Each SEP will enter into an agreement with the designated evaluation resource and comply with all data collection and reporting requirements of the governing municipality and DHAS/DHSS determined to be necessary to evaluate the operation of the Program.

a) Reporting Requirements. Each municipality shall adhere to various reporting requirements as set forth below:

i) Monthly Reports. Each SEP, through the municipality, must submit a monthly report to the DHSS/DHAS by no later than 15 days into the subsequent month. The monthly report will, at a minimum, routinely account for Program utilization, including, but not limited to, peak periods, slowest exchange days, etc., and present a summary of participant demographics for the month reporting. Participant demographics includes the characteristics of those who use the Program, including age, race, ethnicity,

gender, and home zip code, and information as required by evaluation project protocol, such as drug treatment status at point of entering SEP, drug and sexual risk behaviors, and involvement in other public health and social services;

ii) Six-Month Evaluation Reports. Each SEP, through the municipality, must submit a six-month report of activities to the DHSS/DHAS no later than 30 days after the end of each six-month period. Six-month evaluation reports shall include, but not be limited to:

A) The number of enrolled participants;

B) Aggregate demographic information on the characteristics of Program participants as required by evaluation project protocol, such as age, race, ethnicity, gender, and home zip code, drug treatment status at point of entering SEP, drug and sexual risk behaviors, and involvement in other public health and social services;

C) The number of syringes distributed to participants, including the average number distributed per participant per transaction;

D) The number of syringes returned by participants, including the average number returned per participant per transaction;

E) The number and types of services either directly provided or provided by referral to participants, not limited to referrals for HIV counseling and testing; health care services, including evaluation and treatment for HIV infection, sexually transmitted diseases and tuberculosis; family planning; obstetrical and prenatal care; social services; drug abuse treatment services, and hepatitis.

F) Any significant problems encountered; and

G) Any significant Program successes achieved.

iii) Final/Annual Report. It is expected that each SEP, through the municipality, will submit an annual report of activities, summarizing the information provided on a monthly basis. Annual reports shall contain an evaluation of the organization's progress in attaining the Program's goals. The final/annual report must be submitted by the SEP, through the governing municipality, to the DHSS/DHAS no later than 60 days after the close of the State fiscal year (June 30).